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SECTION 6A – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR

NOTE: All entities must also complete Section 5A, Questions 1 and 2, above (APHIS/CDC Form 1)

49. All entities must answer the following questions for each BSL-4 laboratory for each Principal Investigator:

a. Activities conducted under BSL-4 containment (check all that apply):

☐ Research ☐ Diagnostic ☐ Large scale production ☐ Small animal ☐ Large animal

☐ Recombinant DNA ☐ Other (give description): _____

b. How many separate BSL-4 laboratories are you registering for select agent work?

☐ 1 laboratory ☐ 2 laboratories ☐ 3 or more laboratories

c. Are these laboratories currently registered with the CDC Select Agent Program? ☐ Yes ☐ No

d. Are these BSL-4 laboratories currently operational (presently conducting BSL-4 work)? ☐ Yes ☐ No

If no, date of anticipated completion of laboratories: _____

e. What type of BSL-4 laboratories are you registering?

☐ Protective suit laboratory ☐ Stand alone Class III cabinet laboratory

☐ Protective suit laboratory with associated Class III cabinet

50. Include a floor plan for each BSL-4 laboratory, Class III cabinet laboratory, or ABSL-4 laboratory where select agents are to be used or stored.

Floor plan(s) must include:

a. Sink locations ☐ Yes ☐ No

b. Eyewash locations ☐ Yes ☐ No

c. Laboratory furniture locations (including bench work) ☐ Yes ☐ No

d. Biosafety cabinet (BSC) locations ☐ Yes ☐ No

e. Fume hood locations ☐ Yes ☐ No ☐ N/A: No fume hoods

f. HVAC supply and exhaust locations ☐ Yes ☐ No

g. Freezer/refrigerator locations (include LN2 storage) ☐ Yes ☐ No

h. Other large equipment locations (e.g., incubators, centrifuges) ☐ Yes ☐ No

51. Provide information on the biosafety cabinets in use (attach additional sheets if needed):

a. Class of cabinet: ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ Class III

b. Biosafety cabinet connection to the HVAC system: ☐ Hard ducted ☐ Thimble ☐ Re-circulating

c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____

52. Provide a description of the BSL-4 HVAC system (*check all that are appropriate*):

a. ☐ Single-pass

b. ☐ Dedicated exhaust

c. ☐ Constant air volume ☐ Variable air volume

d. ☐ Redundant exhaust fans

e. ☐ Emergency power back-up

53. Vacuum lines contain HEPA filters: ☐ Yes ☐ No ☐ No vacuum lines are used

54. A medical surveillance system is in place for laboratory personnel using select agents for toxins: ☐ Yes ☐ No

55. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director: ☐ Yes ☐ No

56. A sharps policy is in place for this laboratory: ☐ Yes ☐ No

57. A site-specific emergency operations plan is available for this laboratory: ☐ Yes ☐ No

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58. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with select agents at this entity: ☐ Yes ☐ No

    a. If yes, has IBC approved the work proposed in this application: ☐ Yes ☐ No

    b. The laboratory has been inspected by USDA, FDA, CLIA, DoE, DoD or others: ☐ Yes ☐ No

    c. If yes, then give agency and date of last inspection(s): _____

59. Briefly state (no more than a paragraph) the objectives of the work with the select agents or toxins, including a description of the methodologies or laboratory procedures that will be used. State if any host-vector systems will be used. Specify whether work will involve live agents and recombinant DNA:

60. Provide general facility and safety information for the BSL-4 laboratory facility (ies) you are registering by answering the questions in this section. Use separate sheets if necessary.

    a. BSL-4 laboratory design and operational procedures are documented and re-verified annually: ☐ Yes ☐ No

    b. A specific BSL-4 facility operations manual has been prepared: ☐ Yes ☐ No

    c. All standard BSL-4 microbiological practices are followed: ☐ Yes ☐ No

    d. There is a mandatory daily inspection of the containment parameters for the BSL-4 laboratory area(s) and critical life support systems: ☐ Yes ☐ No

    e. Walls, floors, and ceilings of the BSL-4 laboratory rooms are sealed. All penetrations into the laboratory are sealed: ☐ Yes ☐ No

    f. The HVAC system is dedicated and is not re-circulated: ☐ Yes ☐ No

    g. There is a visual and auditory alarm system provided to alert facility workers to system malfunctions and/or failures of containment parameters: ☐ Yes ☐ No

    h. Entry to the laboratory is through a double set of lockable, self-closing doors: ☐ Yes ☐ No

    i. Each protective suit or cabinet laboratory room has a hands-free sink: ☐ Yes ☐ No

    j. There is a double door autoclave for decontamination of materials from the suit lab and/or the Class III cabinet and cabinet room: ☐ Yes ☐ No

    k. A visual pressure differential monitoring system is provided at the clean change room for laboratory personnel to verify directional air before entry into the BSL-4 laboratory: ☐ Yes ☐ No

    l. Differential pressures/directional airflow between adjacent areas is monitored and alarmed (visually and audibly) to indicate system failure: ☐ Yes ☐ No

    m. Double HEPA filtration of all suit area, decontamination shower, decontamination airlock and Class III cabinet exhaust air is in place: ☐ Yes ☐ No

    n. Single HEPA filtration of all suit area, decontamination shower, decontamination airlock and Class III cabinet supply air is in place: ☐ Yes ☐ No

    o. Describe method utilized for decontamination of BSL-4 area(s):

    p. Inactivation of organisms and materials removed from BSL-4 containment is accomplished by what methods?

    ☐ Irradiation ☐ Chemical disinfection ☐ Autoclaving ☐ Other

    Describe: _____

    q. Inactivation of materials removed from BSL-4 containment is verified: ☐ Yes ☐ No

    Describe: _____

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Facilities registering a laboratory containing a Class III cabinet, must answer question 61. Facilities wishing to register protective suit laboratories and suit laboratories with associated Class III cabinets must also answer question 62.

61. Entities registering a **stand alone Class III cabinet laboratory** must verify the following items:

a. Entry to the laboratory housing the Class III cabinet is through a double set of lockable, self-closing doors: ☐ Yes ☐ No

b. Inner and outer change rooms are separated by a shower for personnel entering and leaving the cabinet room: ☐ Yes ☐ No

c. There is a double-door (pass-through) autoclave, dunk tank, fumigation chamber, or ventilated anteroom for passing materials, supplies, or equipment into or out of the cabinet room: ☐ Yes ☐ No

d. Walls, floors, and ceilings of the cabinet room(s) are sealed and all penetrations into the cabinet room(s) are sealed: ☐ Yes ☐ No

e. Floors are seamless and coved: ☐ Yes ☐ No

f. All drains in the cabinet room(s), inner change room(s), and autoclave chambers connect directly to an appropriate liquid waste decontamination system: ☐ Yes ☐ No

g. Sewer vents and other service lines contain HEPA filters: ☐ Yes ☐ No

h. Bench tops are seamless or sealed surfaces that are impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and other decontaminant chemicals: ☐ Yes ☐ No

i. Laboratory furniture is capable of supporting anticipated loads and uses and is covered with a non-fabric material that can be easily decontaminated: ☐ Yes ☐ No

j. A hands-free sink is located in the cabinet room(s) near the door and in the inner and outer change room: ☐ Yes ☐ No

k. If a central vacuum system is present, it serves only the cabinet room(s) and is HEPA filter protected, and liquid and gas services to the cabinet room are protected by backflow prevention devices: ☐ Yes ☐ No

l. Any windows are break resistant and sealed: ☐ Yes ☐ No

m. Double-door autoclaves are provided for decontamination of materials removed from the Class III cabinet and the cabinet room. These autoclaves are interlocked so that the outside door can only be opened after the sterilization cycle is complete: ☐ Yes ☐ No

n. Pass-through dunk tanks, fumigation chambers, or equivalent decontamination methods are provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from both the Class III biological safety cabinet(s) and the cabinet room(s): ☐ Yes ☐ No

o. All HEPA filters are tested and certified annually: ☐ Yes ☐ No

p. An HVAC monitoring system is provided to avoid pressurization of the laboratory and is alarmed to warn laboratorians of exhaust system failure: ☐ Yes ☐ No

q. There is HEPA filtration of all supply and exhaust air from the cabinet room(s), inner change room(s), and anteroom(s): ☐ Yes ☐ No

r. The Class III cabinet is directly connected to the exhaust system with HEPA filtration on the supply and double HEPA filtration on the exhaust: ☐ Yes ☐ No

s. Appropriate communication systems are provided between the laboratory and external personnel (intercom, phone, fax, and computer): ☐ Yes ☐ No

62. Entities registering a **protective suit laboratory or a protective suit laboratory with associated Class III cabinet registration** must verify the following items (**suit laboratories with associated Class III cabinets must also answer question 61**):

a. Entry into the area(s) where work is performed with BSL-4 agents [suit room(s)] is through a series of changing and decontamination areas separated by airtight doors: ☐ Yes ☐ No

b. Inner and outer change rooms are separated by a personal shower: ☐ Yes ☐ No

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c. A chemical shower is provided for decontaminating the outer surface of the protective suit: ☐ Yes ☐ No

d. A breathing air system is provided with redundant compressors, backup storage tanks, HEPA filtration protection, and alarm monitoring in the event of failure: ☐ Yes ☐ No

e. All penetrations into containment shell (walls, floors, and ceilings) of the suit area(s), chemical shower(s), and airlock(s) are sealed: ☐ Yes ☐ No

f. Daily inspections of the containment parameters and life support systems are performed, completed and documented before laboratory work begins: ☐ Yes ☐ No

g. A double-door, interlocked autoclave is provided for decontaminating waste materials removed from the suit area(s): ☐ Yes ☐ No

h. A dunk tank, fumigation chamber, or ventilated airlock to pass materials, supplies, or equipment into or out of the suit area(s): ☐ Yes ☐ No

i. Bench tops are seamless surfaces that are impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and other decontaminant chemicals: ☐ Yes ☐ No

j. Laboratory furniture is capable of supporting anticipated loads and uses and is covered with a non-fabric material that can be easily decontaminated: ☐ Yes ☐ No

k. A hands-free sink is located in the suit area(s): ☐ Yes ☐ No

l. If a central vacuum system is present, it serves only the suit area(s) and is protected by HEPA filtration: ☐ Yes ☐ No

m. Liquid and gas services to the suit area(s) are protected by backflow devices: ☐ Yes ☐ No

n. Inner and outer doors to chemical showers and airlocks are interlocked to prevent both doors from being opened at the same time: ☐ Yes ☐ No

o. Any windows are break resistant and sealed: ☐ Yes ☐ No

p. All drains in the suit area(s), chemical shower(s), and autoclave chambers connect directly to an appropriate liquid waste decontamination system: ☐ Yes ☐ No

q. An HVAC monitoring system is provided to avoid pressurization of the laboratory and is alarmed to warn laboratorians in the event of exhaust system failure: ☐ Yes ☐ No

r. Redundant exhaust fans are installed: ☐ Yes ☐ No

s. All HEPA filters are tested and certified annually: ☐ Yes ☐ No

t. HVAC supply to the suit area(s), chemical shower(s), and airlock(s) is HEPA filtered: ☐ Yes ☐ No

u. HVAC exhaust from the suit area(s), chemical shower(s), and airlock(s) is double HEPA filtered with the HEPA filters in series: ☐ Yes ☐ No

v. Appropriate communication systems are provided between the laboratory and external personnel (intercom, phone, fax, and computer): ☐ Yes ☐ No

w. Emergency lighting and emergency communications systems are provided for the BSL-4 areas: ☐ Yes ☐ No

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63. Entities registering an **ABSL-4 laboratory** must provide the following information. Entities registering a **stand alone Class III cabinet** for housing animals infected with biosafety level 4 agents, or other ABSL-4 use must complete **question 61** above. Entities registering a **protective suit laboratory** housing animals infected with Biosafety level 4 agents must complete **question 62 as well as the following**:

a. List animal models in use for ABSL-4 experiments: _____

b. ABSL-4 laboratory room(s) designations: _____

c. Specific procedures have been developed for handling animals under ABSL-4 conditions in the Class III cabinet or protective suit laboratories being registered: ☐ Yes ☐ No

d. All appropriate special policies and procedures are approved by the Institutional Animal Care and Use Committee: ☐ Yes ☐ No

e. Aerosol experiments are conducted in this ABSL-4 laboratories: ☐ Yes ☐ No

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f. Describe how animals are housed under ABSL-4 conditions (add additional sheets as necessary):

g. Cage washing is with a mechanical cage washer: ☐ Yes ☐ No

h. Cage washing area is shown on the floor plans: ☐ Yes ☐ No

i. Waste (e.g., carcasses, sewage, bedding, etc.) is sterilized before disposal: ☐ Yes ☐ No

Describe treatment method:

j. Method of disposal of treated carcasses: ☐ Incineration ☐ Rendering ☐ Chemical decomposition

☐ Other (*describe*):

k. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

l. Appropriate personal protective equipment is used: ☐ Yes ☐ No

m. Personnel assigned to work with infected animals work in pairs: ☐ Yes ☐ No

SECTION 6B – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ALL ENTITIES (TRAINING AND SECURITY)

64. Training:

a. Site-specific security training is provided to individuals with access to areas where BSL-4 select agents are handled or stored: ☐ Yes ☐ No

b. Site-specific safety training is provided to individuals with access to areas where BSL-4 select agents are handled or stored: ☐ Yes ☐ No

c. A biosafety manual has been prepared that indicates special hazards associated with the BSL-4 agents in use and laboratory personnel are required to read and follow these practices and procedures: ☐ Yes ☐ No

d. Training is provided to laboratory personnel prior to beginning work with BSL-4 select agents: ☐ Yes ☐ No

e. Training is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency):

f. Written records of individuals trained are kept: ☐ Yes ☐ No

g. Personnel are required to demonstrate proficiency in laboratory procedures prior to working with BSL-4 select agents: ☐ Yes ☐ No

h. Please provide a brief description of the individual training program for BSL-4 laboratory personnel (attach additional sheets if necessary):

65. Security:

a. Provide a brief explanation of the system in place to detect loss or theft of select agent(s):

b. All viable BSL-4 agents are stored within the BSL-4 containment area: ☐ Yes ☐ No

If no, then provide list of rooms where BSL4 agents are stored:

c. Storage areas within BSL-4 containment are under surveillance: ☐ Yes ☐ No

d. Describe type of surveillance:

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66. There is a site-specific security plan for each of the BSL-4 laboratories listed above: ☐ Yes ☐ No

a. Only persons whose presence in the BSL-4 laboratory facility or individual laboratory rooms is required for program or support purposes are authorized to enter: ☐ Yes ☐ No

b. Access to the laboratory is controlled by locked doors: ☐ Yes ☐ No

c. A log book indicating date and time of entry and exit of all personnel to and from the BSL-4 containment area is maintained: ☐ Yes ☐ No

d. Indicate means of limiting access to buildings with BSL-4 laboratories using select agents:
☐ Guard station at the entity entrance
☐ Card access system or locks
☐ Other (describe): _____

e. Indicate means of limiting access to select agents once inside the building:
☐ Door to laboratory is locked
☐ Guard station at the building entrance
☐ Card access system or locks
☐ Other (describe): _____

f. Means to limit access to select agents once inside the laboratory:
☐ Locked incubators, refrigerators, freezers, etc.
☐ Other (describe): _____

g. Means to limit access to select agents in storage:
☐ Storage area door locked
☐ Lock boxes
☐ Other (describe): _____

h. Means to monitor unauthorized entry into the BSI-4 laboratory where select agents are used or stored:
☐ Electronic logs of card access system entries are reviewed for unusual activity
☐ Manual sign in and out logs are kept and monitored
☐ Camera surveillance (e.g., CCTV)
☐ Security alarm system that directly monitors the laboratory
☐ Other (describe): _____

i. The laboratory is secured when no one is present during regular working hours: ☐ Yes ☐ No

j. The laboratory is secured when no one is present after regular working hours: ☐ Yes ☐ No

k. Total number of personnel with access to BSL-4 area during operations: _____

l. Individuals not directly involved in research activities have access to select agents: ☐ Yes ☐ No

If yes, please explain: _____

m. Non-laboratory personnel (visitors, including janitorial and facility maintenance personnel) have access to the laboratory with select agents: ☐ Yes ☐ No

If yes, are they allowed into the laboratory unescorted? ☐ Yes ☐ No

If yes, please explain: _____

n. Describe how the entity limits access to the laboratories where select agents are being manipulated and stored to only authorized and qualified persons:

_____

SECTION 6C – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ENTITIES WORKING WITH INFECTIOUS AGENTS

67. Provide an estimate of the maximum quantities (e.g., number of petri dishes or total volume of liquid media) and concentration of organisms grown at a given time (e.g., 2 - 250 ml flasks of 10^5 cfu/ml):

_____

68. All cultures, stock and other regulated wastes are decontaminated before disposal by an approved sterilization method: ☐ Yes ☐ No

If yes, describe method: _____

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SECTION 6D – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ENTITIES WORKING WITH RECOMBINANT DNA OR GENOMIC MATERIAL

69. This laboratory meets NIH guidelines for research involving recombinant DNA molecules: ☐ Yes ☐ No

70. Will you possess, use or transfer the following:

    a. Nucleic acids that can produce infectious forms of any of the select agent viruses. ☐ Yes ☐ No

    b. Recombinant nucleic acids that encode for the functional form(s) of any select toxins if the nucleic acids:

        1) can be expressed in vivo or in vitro. ☐ Yes ☐ No

        2) are in a vector or recombinant host genome and can be expressed in vivo or in vitro. ☐ Yes ☐ No

    c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☐ No

71. Do you intend to conduct the following experiments:

    a. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. ☐ Yes ☐ No

    b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD_{50} < 100 ng/kg body weight. ☐ Yes ☐ No

72. Provide a brief description of the recombinant constructs and any associated expression control elements, including what the recombinant DNA encodes for, if known: _____

73. Give an estimate of range of length of recombinant DNA to be used: _____

SECTION 6E – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ENTITIES WORKING WITH SMALL ANIMALS

74. List species of small animals that will be used: _____

75. Describe route of infection: _____

76. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No

    If yes, describe method: _____

77. The entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this laboratory: ☐ Yes ☐ No

    a. If yes, the proposed work with select agents in small animals has been approved by the IACUC: ☐ Yes ☐ No

    b. The laboratory space is accredited by AAALAC: ☐ Yes ☐ No

    c. If yes, give inspection date: _____

SECTION 6F – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ENTITIES WORKING WITH LARGE ANIMALS

78. List species of large animals that will be used: _____

    a. Describe route of infection: _____

    b. Carcass of animals are disposed in a manner to preclude their use as food for human beings or animals: ☐ Yes ☐ No

    c. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No

    If yes, give method: _____

79. Carcass of animals are disposed on site: ☐ Yes ☐ No

80. The entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this entity: ☐ Yes ☐ No

    If yes, the proposed work with select agents in large animals has been approved by the IACUC: ☐ Yes ☐ No

81. The laboratory space is accredited by AAALAC: ☐ Yes ☐ No

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SECTION 6G – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH TOXINS

82. A Chemical Hygiene Plan is available for the laboratory using toxins: ☐ Yes ☐ No

83. Maximum quantity of each toxin under the control of the principal investigator at a given time: _____

84. Form of toxins used: ☐ Liquid ☐ Lyophilized ☐ Not Applicable-Storage Only

85. The toxin is produced by live agent at the entity: ☐ Yes ☐ No

If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____

86. Dilution procedures and other manipulations of the concentrated toxins are:

a. Conducted in: ☐ Fume hood ☐ Biological safety cabinet ☐ Not Applicable-Storage Only

1) If a fume hood or biosafety cabinet is used, certification is conducted:
Annually Biannually Other (describe): _____

b. Work is conducted with two knowledgeable people present: ☐ Yes ☐ No

87. A hazard sign is posted on the door when toxins are present: ☐ Yes ☐ No

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